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IN THE

Supreme Court of the United States

October Term, 1994

DOW CORNING CORPORATION,

Petitioner,

v.

MARIANN HOPKINS,

Respondent.

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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STATEMENT OF THE CASE

On December 1, 1988, respondent Mariann Hopkins filed suit in the United States District Court for the Northern District of California against petitioner Dow Corning Corporation to recover for injuries she suffered as a result of two sets of Dow Corning breast implants, which she received in breast reconstruction surgery in 1977 and 1986. The 1977 implants burst inside Hopkins' body, flooding her tissues with silicone gel. She sought recovery for bodily injury, including mixed connective tissue disease ("MCTD"), a debilitating autoimmune disease caused by rupture of her silicone-filled implants, and for pain and suffering, medical expenses, and loss of earnings; she also sought punitive damages. *See* Pet. App. at 6-8, 27-30. The primary focus of the case, and the basis for punitive damages, was Hopkins' claim that Dow Corning had fraudulently misrepresented to her, and to the public at large, that its product was safe and tested for use in humans, knowing this to be false. The jury found Dow Corning liable for Hopkins' injuries and awarded her $840,000 in compensatory damages ($473,000 in out-of-pocket losses and $367,000 in pain and suffering damages), plus $6.5 million in punitive damages. *Id.* at 6, 27.

On post-trial motions Dow Corning challenged the verdict on a number of grounds, only one of which it has pursued throughout the appellate process to this Court: its claim that it should receive a new trial because the district court erred in admitting causation testimony from three experts called by Hopkins.[1]

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[1] Dow Corning never moved for a directed verdict on the sufficiency of Hopkins' causation evidence. As demonstrated in Hopkins' brief below, and as Dow Corning has never contested:

> Such an objection appears nowhere in Dow's written Motion for Partial Directed Verdict, filed Nov. 15, 1991 (ER 265); *see also* 9 RT 1109 (limiting directed verdict objections to those appearing in written motion). Moreover, no such objection appeared in Dow's Motion for Judgment as a Matter of Law, filed January 23, 1992 (ER 314). Both the Seventh Amendment and the rule of *Singleton v. Wulff*, 428 U.S. 106, 120-21 (1976), thus flatly bar review on appeal of Dow's sufficiency-of-evidence objection.

Brief of Plaintiff-Appellee, 9th Cir. No. 92-16132, filed Feb. 1, 1993, at 56 n.54. It is well established that the Seventh Amendment bars re-examination

The questions that Dow Corning now attempts to raise are not presented by this case, were not properly presented or passed on in the courts below and, in any event, have no merit. Those points are fully set out below. See pp. 15-26, *infra*. But Dow Corning also raises a broader theme, one not linked in any logical way to the questions presented: a plea that this Court should accept review as a means of correcting some sort of crisis in "mass tort" cases in the lower courts, one that Dow Corning argues is of "national importance." Pet. at 12-18. This argument — which in any event should be presented to Congress or to state legislatures — cannot save Dow Corning's defective petition, for the need for the supposed "remedies" it advocates as a legislative solution is simply not one that applies to this case, as a brief review of the evidence not addressed by Dow Corning makes clear.

A. *The Evidence Concerning Punitive Damages*

In Dow Corning's view, "[m]ass product liability litigation" follows "a well-documented pattern" in which a large jury verdict including punitive damages spawns further widespread litigation, despite the litigation's evident lack of real merit, Pet. at 13-14 & n.9, creating an unwarranted "overburden on judicial systems." *Id.* at 16 n.13. Dow Corning suggests that the fear of huge and unjustified punitive damages verdicts against out-of-state corporations, based on bias and deep pockets, is especially justified in these kinds of cases. *Id.* at 17.

As part of an effort to suggest that the punitive damages verdict in *this* case is part of an alleged national problem, Dow

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of a jury's verdict on a sufficiency objection not preserved at the directed verdict stage. *See, e.g.*, *Baltimore & Carolina Line v. Redman*, 295 U.S. 654, 657-58 (1935); *Slocum v. New York Life Ins. Co.*, 228 U.S. 364, 376-80 (1913); *Parsons v. Bedford*, 28 U.S. (3 Pet.) 433, 446-48 (1830) (Story, J.); *Mallick v. International Broth. of Elec. Workers*, 644 F.2d 228, 233 (3d Cir. 1981); *Sulmeyer v. Coca Cola Co.*, 515 F.2d 835, 846 n.17 (5th Cir. 1975), *cert. denied*, 424 U.S. 934 (1976); *Guerrero v. American-Hawaiian Steamship, Co.*, 222 F.2d 238, 243-44 (9th Cir. 1955); *Mutual Ben. Health & Accident Ass'n v. Thomas*, 123 F.2d 353, 355 (8th Cir. 1941).

Corning claims that the Ninth Circuit's opinion "stated a number of assumed facts that were supported only by the arguments of respondent's counsel," for example, the view that thousands of women were "'at risk of encountering the same fate from which Hopkins suffered,'" and that there was "'evidence that [petitioner] gained financially from its conduct.'" Pet. at 12 n.8 (quoting Pet. App. at 30). To the contrary, at trial Hopkins produced ample evidence, mainly from Dow Corning's own files and employees, to support each and every statement made by the court of appeals implicating Dow Corning in a fraudulent course of conduct. The record demonstrates that for more than a decade Dow Corning, in the pursuit of profit, distributed a product to be placed in women's bodies while knowing that its safety had not been meaningfully tested, knowing that negative safety results were being withheld from the public, knowing that employees were affirmatively lying to customers about safety, and knowing that the public was relying on these misrepresentations, thus endangering many thousands of women. *See* Pet. App. at 8-10, 30. For example:

(1) Dow Corning recklessly "rushed development of silicone gel implants." Pet. App. 8.

Before 1972, Dow Corning was the sole manufacturer of gel-filled breast implants and enjoyed 100 percent of a market worth millions of dollars annually. 6 Reporter's Transcript ("RT") 616:10-11, 615:15. In 1972, however, competitors introduced new implants with a softer, more "natural" feel. Surgeons (the market for implants, 1 RT 73:16-21) quickly decided that Dow Corning's product was "out of style, out of touch." 1 RT 73:5-7. Consequently, competitors "gained a large market share quickly," 6 RT 578:3-4, and Dow Corning suffered "erosion in the market share." 6 RT 578:14-15. "In 1974, the competitive position became very severe," leading Dow Corning to create a special Task Force to "make a product that would be more competitive." 6 RT 575:9-10, 576:3-4.

The crash effort was designed to rush to market an entirely new product in less than five months. Thomas Talcott, a veteran Dow Corning engineer who was rated in the best one percent of Dow Corning employees, 4 RT 573, testified that the weekly

meetings were "charged with bottom line profit" — the "urgency of getting these products on the market to maintain and recover market share." 6 RT 615:10-12. *See also* Plaintiff's Exhibit ("PX-") 55 (collecting Task Force memos and minutes demonstrating members' sense of urgency and constant corner-cutting on safety in the race to market). Talcott testified that his repeated warnings about the product's dangers were ignored by Dow Corning officials, and that Dow Corning's response was to penalize Talcott for raising trouble.[2]

(2) Dow Corning "implants experienced a high rate of rupture" and "leakage." Pet. App. 8-9.

The danger that implants would rupture, pouring silicone gel directly into a woman's body tissue, was clearly known to

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[2] For example, the Task Force rushed into initial experimental implantation in women without giving careful deliberation to quality standards (PX-55 at 2957-58, 2960); it adopted a "single dip" method for making envelopes that guaranteed "bubbles and flaws" because it was "easier" and "cheaper" than the "multiple dip" method that would prevent defective envelopes (6 RT 612:1-18, Pet. App. at 9); it regarded as "allowable flaws," under product specifications, "gross thin spots and . . . significant bubbles" that contributed to implants bursting even as they were being inserted (PX-112); and it ignored concerns that the gel inside the envelope was "extremely fluid in nature" so that "when the devices broke" it would "end up being nonretrievable in people." 6 RT 610:12-16, 611:1-2. Dow Corning ignored these dangers despite the "high rate of rupture" experienced during the initial experimental implants in women. 6 RT 614:6-7. No one on the Task Force, or in higher management, heeded the concerns about these and other dangers that were expressed by Talcott. 6 RT 624:1-7. Talcott "complained . . . vigorously about the introduction of this product" directly to Dow Corning's Director of Research, but to no avail. 6 RT 611:9-20. Instead, at the conclusion of his ten-month effort to prevent Dow Corning from introducing a dangerous product, Talcott was demoted in performance rating from one of Dow Corning's best-rated employees to one of its worst. 6 RT 573. Soon after, he resigned. 6 RT 618:4-5.

In 1975, when Dow Corning launched its product, the Food and Drug Administration ("FDA") lacked power to regulate implanted medical devices, and during all times relevant to this lawsuit Dow Corning's distribution of breast implants was unconstrained by FDA action. Fifteen years after promulgation of the Medical Device Amendments of 1976, 21 U.S.C. § 360c, the FDA ordered that "commercial distribution of [breast implants] must cease" unless each manufacturer could prove the safety of its product. *See* 56 FR 14,620 (April 10, 1991) (final rule). In response, Dow Corning ceased distribution.

Dow Corning at the time it was rushing its product to market, and at all times thereafter. Dow Corning did nothing either to solve these problems or to alert the public to them; instead, it did its utmost to hide them. For example, "several devices . . . ruptured as a surgeon was trying to put them in" during initial experiments with women in early 1975. 6 RT 614:6-7. Nearly a year later, two implants "broke during augmentation surgery for the TV taped demonstrations." Pet. App. at 9 (quoting PX-112). There was the further problem of implant aging: Dow Corning knew that after just two years on the shelf the ability of its implants to resist tearing decreased more than 75 percent. 4 RT 302-03. Moreover, Dow Corning's top management knew that vulnerability to rupture increased once an implant was in a woman's body and was subjected to "elastomer-swell," and that there had even been "cases where the envelope had been 'dissolved by' or 'absorbed by' the gel." PX-87; *see also* 4 RT 299-301. Indeed, given these kinds of problems, Dow Corning's implants could be expected to last only *five years* before they would fail inside a woman. 4 RT 297:1-7.[3]

Dow Corning was also well aware of an entirely different means by which silicone could escape from the envelope, known

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[3] The poor design of the envelope was palpably demonstrated shortly after marketing began, as reports arrived at Dow Corning in increasing numbers about ruptures of the new implants, which directly exposed women to the large amounts of liquid silicone contained in the implants. For example, in 1977 the head of the Task Force noted a number of recent cases involving "broken envelopes and gel found in the pocket," along with claims that the gel had "caus[ed] a reaction, infection, etc." PX-95, at 1376. Dow never published these reports, or the failure rate of its implants: "the data existed within corporate files, but they were never made public." 5 RT 408:7-10. Instead, with full knowledge of this rupture problem, for a full decade Dow Corning marketed its new implants with a "Facts You Should Know" pamphlet specifically written for women and listing "the questions most women ask about breast implants and the answers." PX-3, at 480. The pamphlet stated: "**Q. How long will the implants last? A.** Based on laboratory findings and human experiences to date, a gel-filled implant should last for a lifetime." *Id.* Hopkins was one of the many women who relied on, and was deceived by, this assurance of safety. 6 RT 669, 670:8-9. *See also* 2 RT 135:15-18. The package insert, addressed to surgeons, warned only of the risk of "excessive breast firmness and/or discomfort," not any risk of rupture. PX-1, at 3.

as "gel bleed": the tendency of the silicone gel to leak right through the envelope that was supposed to contain it. Just before its latest model breast implant was released in 1975, some surgeons "noted that after the[y] had been handled for awhile, the surface became oily"; indeed, "some [implants] were bleeding on the velvet in the showcase." PX-55, at 3032. Because Dow Corning was eager to get the product out "on time," the leader of the Task Force made no attempt to solve the problem and simply instructed salesmen to hide it from surgeons when pitching the product. They were instructed in writing to "be sure samples are clean and dry before customer detailing" and "*wash [the implants] with soap & water* in nearest washroom, *dry with hand towels*." PX-55, at 3043 (emphasis added); *see also* Pet. App. at 9. Dow Corning affirmatively worked to cover up this problem in several other ways.[4]

(3) Dow Corning "had knowledge of the harmful effects of silicone on the human body" which it affirmatively concealed from the public. Pet. App. 9-10.

Dow Corning's awareness of the rupture and gel bleed problems was significant in light of its knowledge about the

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[4] In 1976, the same Task Force leader who instructed salesmen to "wash and dry" the implants to remove the gel bleed asserted to a surgeon researcher that the gel bleed phenomenon was "physically impossible." The researcher had discovered the problem on his own, and Dow Corning worked hard to convince him to hold off on publishing his findings. PX-99 at 1-2. The Task Force leader wrote a memo to other employees expressing worry that, if the report was published, the medical and legal communities "may interpret this as proof that our gel causes problems." PX-97 at 1. Soon thereafter, Dow Corning learned that *another* surgeon was proposing to do his own study on the extent of gel bleed and the effects of gel bleed fluid in animals. PX-98 at 1. The Task Force leader worried that this research could be "embarrassing" and possibly "detrimental," *id.*, and Dow Corning ultimately chose to bring the surgeon to corporate headquarters to "convey the impression that we are indeed working in this area" and to indicate "candid reservations" about his proposed independent research. PX-69. At the same time, the Dow Corning scientist in charge of the gel bleed problem decided that the company's data would not "even be considered for release" except after further delay and after approval by top management, given the "obvious sensitivity" of the data and the "severe repercussions in the public sector" that could result from candid disclosure of the gel bleed problem. *Id.*

dangers of liquid silicone. According to one of Dow Corning's top scientists, its new gel implants were about 90 percent liquid silicone by weight, so that the gel was "nothing more than *a delivery system for liquid silicone*." 15 RT 2093:14-19, 2095:15-16 (emphasis added). Dow Corning was well aware of the dangers of liquid silicone to humans. For more than a decade, published medical studies and Dow Corning's own testing had revealed silicone's harmful tendency to migrate from an initial site throughout the human body, and to seriously disrupt the immune system. These studies and tests were corroborated by numerous animal studies, which revealed an immune system response triggered by the same type of silicone contained in Dow Corning's implants. At least six published articles demonstrated these pathological effects. 2 RT 243-44. At the same time, there were clinical reports of cases of "humans who had been injected with silicone fluid . . . showing full-blown reactions attributed to silicone in people that were leading to involvement of the immune system." 2 RT 244.[5]

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[5] The first carefully executed study on liquid silicone confirmed in 1968 that immune reactions can result from silicone in the human body and that silicone migrates to organs that are part of the immune system. 2 RT 261-62. Dow Corning's own animal studies had demonstrated during 1965-68 that silicone tended to concentrate in the lymphatic system and produced a cellular reaction, "which is a hallmark or indicator of a possible immune response." 2 RT 250. *See also* 15 RT 2052:20-22 (concession of Dow Corning's own expert that "distribution of silicone to major organs in the body" was found in study PX-47). One study (DX-60) showed distribution through major organs, including the lymphatic system, and found that *three* of eleven test dogs developed chronic thyroiditis, an autoimmune disease. 15 RT 2049-51. Yet another animal test with 35 dogs, PX-146; 15 RT 2064-65, yielded *four* dogs which "had developed chronic thyroiditis"; indeed, "at the end of the three-year period most of the dogs were [on a] downward trend." 15 RT 2069.

Thus, by the end of the 1960s — more than seven years before Hopkins received her first set of implants — Dow Corning itself perceived significant risks that silicone placed in a human being would migrate throughout the body, collect in organs composing the immune system, and result in adverse cellular reactions indicative of chronic immune reaction. 2 RT 262. Dow Corning's research on the effects of silicone continued into the 1970s up to marketing of its new, lower profile, more liquid implant in 1975. *See, e.g.*, 15 RT 2060 (Dow Corning's own expert admitted that Dow Corning was aware by 1972 that silicone gel would migrate in animals and that there was evidence that silicone would travel to tissues included in the lymphatic and immune systems);

(4) Dow Corning "knew long-term studies of the implants' safety were needed, . . . concealed this information as well as the negative results of the few short-term laboratory tests performed, and . . . continued for several years to market its implants as safe despite this knowledge." Pet. App. 30.

Throughout the time it marketed breast implants, Dow Corning knew that it had *no* meaningful scientific data demonstrating that the implants were safe for use in women. Yet it hid this fact and, worse, without scientific support represented its product as proven to be safe for women.

For example, in just the first year of marketing a key Dow scientist complained in three separate memos, over a span of several months, that Dow Corning was "engulfed in unqualified speculation" concerning safety so that "[n]othing to date is truly quantitative or qualitative," PX-63, ¶ 2; that he had "suggested verbally and in writing that we better get going on a basic long range project relative to gel, its formulation, toxicology, etc.," PX-62; and that he had "proposed again and again that we must begin an indepth study of our gel, envelope, and bleed phenomenon. . . . Time is going to run out for us if we don't get underway." PX-64. These concerns were ignored. Indeed, Dow Corning flouted the standard safety practice of conducting a "lifetime" animal study of a substance (7 years for a dog, 2 years for rats or mice, 2-3 years for a rabbit) before permanently implanting it in humans. 3 RT 41:15-21. Using women as, in effect, human guinea pigs, for the first twelve years that it marketed its new breast implants to many thousands of women, Dow Corning did not test them in any animal for longer than *80 days*. 15 RT 2093.

In its quest for market share and profits, Dow Corning zealously misrepresented its product as safe and worked to thwart independent inquiries into its safety. As a Dow Corning

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3 RT 30:8-20, PX-50 (1972 Dow Corning memorandum indicated that liquid silicone injected into rats produced widespread deposit of silicone throughout the immune systems of rats); 3 RT 34-35 (1974 internal Dow Corning study demonstrated that "silicone has the capacity for stimulating the immune system, specifically the antibody producing arm of the immune system").

salesman candidly testified at trial, if he "told the physician that the long-term physiological effects of silicone are unknown, it would be pretty hard to sell" the implants. 1 RT 68:13-16. Surgeons relied for safety information on contact with Dow Corning's sales force, package inserts, periodic letters, and information pamphlets for patients. 2 RT 133-34, 137-38. Dow Corning perpetuated its scheme through these and other means.

Perhaps most egregious was Dow Corning's handling of the results of a two-year study on four dogs that had received older versions of its breast implants, a study that was completed in 1970. 2 RT 265-70; PX-26. In findings that were "absolutely typical of findings made throughout Dow Corning's testing of plastic gel implants," 3 RT 25:12-13, the raw results of the study indicated that at the end of two years "each of the animals had chronic inflammations at all of the sites of the implants," demonstrating "the existence of . . . an immune reaction." 2 RT 269, 275:2-3. Dow Corning sat on these results for three years. Then, when it published the study in 1973 (PX-166), it rewrote the results to its liking. It falsely indicated "that there was no inflammation at the sites of the implants" at the end of 24 months, 2 RT 275:4-6; PX-166 at 101, and that "[a]fter 2 years the normal health of the dogs was confirmed by close examination." PX-166 at 101.[6]

By 1977, uncertainty concerning the adequacy of Dow Corning's testing and the safety of its implants was "costing Dow business," according to one Dow Corning employee who

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[6] The published version of this study was a blatant attempt to convince plastic surgeons and other medical professionals that Dow Corning's breast implants were safe when Dow Corning clearly knew otherwise. The article stated that Dow Corning's implant has "a 10-year history as a safe and efficacious surgical implant," and further asserted that "plastic surgeons have accepted it generally as a safe and effective device." PX-166, at 100, 103. Expert testimony at trial established that the published study went "a long way towards reassuring [readers] about th[e] long-term safety of the implant." 3 RT 24:13-15. If Dow Corning had disclosed the truth at that time, those same readers would have had "grave reservations about proceeding" with implantation in human beings. 3 RT 25:3-4. By covering up these negative results, Dow Corning ensured that the medical community never received early warning signals, known to Dow Corning, that its product was unsafe.

attended an international plastic surgeons' conference. PX-70 at 1. That employee was well aware that a year earlier another Dow scientist had recommended further safety studies, but "[a]s best I can tell *we have not taken significant action* on any of his recommendations." *Id.* (emphasis added). Yet this same employee told an outright lie to the surgeons and then reported the lie to top Dow Corning employees:

> Both presentations [of the other companies on safety issues] were impressive and well received by the 50 Plastic Surgeons present. Several of our customers, looking to us as leaders in the industry, asked me what we were doing. I assured them, *with crossed fingers*, that Dow Corning too had an active "contracture/gel migration" study underway. *This apparently satisfied them* for the moment, but one of these days they will be asking us for the results of our studies.

Id. at 1-2 (emphasis added). Dow Corning presented no evidence at trial that the memo writer was ever punished, or that the lie was ever corrected.

By 1983, Dow Corning had put some order in its pattern of deception, working out "a position statement in response to customer inquiries regarding the safety of the gels." PX-72, at 856. Dow Corning knew that, in fact, "we have no valid long-term implant data to substantiate the safety of gels for long-term implant use," and the best it could do was to use "inferential data" to construct an "argument" that the gel was "basically loosely cross-linked PDMS polymers," which might be regarded as safe. *Id.* at 858.[7] But, of course, Dow Corning never told

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[7] The same memo suggested that another "r[]ationale" for safety was that the gel was "confined in an envelope of silicone elastomer which does have long-term implant history," but the memo also noted that this theory "supposes that ruptures do not occur or are removed quickly," and that experience had demonstrated "this latter assumption to not be accurate." PX-72 at 856. The scientific "argument" in this position paper was put together by the supervisor of Dow Corning's department responsible for conducting biologic testing on breast implants, 15 RT 2136; PX-72 at 858-60, and was endorsed and made Dow policy by Dow Corning's business quality manager. 15 RT 2137:3-5.

its customers that it had only an "argument" that its implants might be safe. As Dow Corning's business quality manager summarized in 1983, in a memo to eight other Dow Corning employees: "[O]ur product literature (attached) on these gels imply that safety testing to qualify them as implant materials *does* exist and can be obtained readily from Dow Corning." *Id.* at 856 (emphasis added). "To our embarrassment," he noted, this simply was not true. *Id.* In a recommendation that would be ignored for another four years, this manager urged "the necessary work to validate that these gels are safe, calling it a "top priority" given "the extensive population of already implanted devices." *Id.* at 857.

A key Dow Corning study conducted in 1985 noted:

> Both the medical community and the United States Food and Drug Administration continue to question the safety of silicones used for [breast implants]. One major concern that has been identified is the fate of the gel when a mammary prothesis is ruptured *in situ*.

This study revealed that silicone gel placed in the rats rapidly broke "into many smaller masses" and migrated throughout the body. PX-36 at 1. After just *168 days* "only 52% of the gel could be recovered." *Id.* Despite the concern of the FDA and the medical community explicitly noted in this study, Dow Corning concealed the study, marking it "proprietary" and barring distribution outside the company without the approval of the [division vice president]." *Id.* (cover sheet). Thus, a full decade after rushing its experimental product to market, Dow Corning continued to conceal from physicians and patients alike the known dangers of its product. On this record, the Ninth Circuit found, "Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award," and "the jury's award of $6.5 million is reasonable." Pet. App. at 30.

B. The Expert Testimony Concerning Causation

As part of its broad overview about the supposed "national importance" of the subject matter of this case, Dow Corning

warns against the danger that district judges will not "meticulously perform their gatekeeping role to prevent 'junk science' from being introduced into evidence." Pet. at 15. On its face, Dow Corning's analysis is plainly far-fetched. For example, Dow Corning lists as supposed examples of this pattern of frivolous burdening of court dockets the litigation over the Dalkon Shield, DES and asbestos, *id.* at 13 n.9 — suggesting that Dow Corning is against *any* mass-tort litigation, no matter how egregious the corporate misconduct and how many people are widely acknowledged to have been injured as a result. In any event, to support the suggestion that *this case* is part of the supposed national problem Dow Corning makes a series of undocumented and highly selective assertions about the expert testimony on causation in this case, assertions that are demonstrably untrue. Although Dow Corning has not presented any threshhold legal issues concerning expert testimony worthy of review, *see* pp. 15-20, *infra*, even if it had done so, its reliance on misrepresentations about the record independently demonstrates the fact-specific and uncertworthy nature of this case.

Prior to receiving her Dow Corning implants in 1977 as a reconstructive measure to ward off potential cancer, Hopkins was in general a vigorous, athletic woman, one who ran three miles a day. 6 RT 680. Within a year after implantation, however, Hopkins began having difficulty running. She lost her stamina; her knees and feet hurt; her fingers intermittently turned white and blue; her neck and joints hurt; her hands were inflamed; and she suffered numerous upper respiratory problems such as bronchitis. 6 RT 683-84; 8 RT 965; 20 RT 34-35. A year later she was diagnosed with mixed connective tissue disease ("MCTD"), a severe autoimmune disorder causing her body's immune system to attack her body's own tissue. 8 RT 964; 9 RT 1054, 1066-70.[8] The pain and fatigue forced her at first to

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[8] Testimony from Hopkins' treating physicians and from medical experts, corroborated by Hopkins, demonstrated that she did not suffer from MCTD before receiving the Dow Corning implants. *See* 8 RT 889:11-15; 9 RT 1104:2-7. *See also* 9 RT 1071-74, 1092-1103, 1256-57. Moreover, expert

cut back her work hours, 8 RT 965-66, 967:11-12, a year later to take medical leave from work, 8 RT 968, 976, and eventually to undergo numerous hospitalizations, frequent physical therapy, and chronic pain. 8 RT 980-84; 9 RT 1075-78; 20 RT 24, 26, 29-31, 37-38, 44-45, 46-51, 102-06. There is no known cure.

At trial, three experts were called by Hopkins to address the cause of her MCTD.

(1) Dr. Nir Kossovsky. Nir Kossovsky, M.D., is a board-certified anatomic pathologist and a faculty member at the UCLA School of Medicine. He is a nationally recognized authority on the effects of silicone breast implants on the human immune system. He is the author of 84 published scientific articles, half of which deal specifically with "the biological reaction to silicones . . . [including] the biological process by which inflammatory reactions are stimulated by silicone." 7 RT 808:25-809:1. He has personally examined over 200 breast implants and the surrounding tissue following removal from human patients. 7 RT 807, 811:25-812:1. He received an award from the Plastic Surgery Research Council for his pioneering work on the immunological activity of silicone in an animal model. 7 RT 812. The FDA panel that reviews the safety data of breast-implant manufacturers hired Dr. Kossovsky as a consultant. 7 RT 806-07. He has also testified on the subject before Congress. 7 RT 810.

Dr. Kossovsky testified at trial that the proper methodology for determining whether or not a patient's MCTD is caused by silicone in breast implants is "a standard established back in 1976," requiring close scrutiny of "the patient's symptoms," the "exposure to the substance," the "evidence of exposure in the tissues," "corroborative evidence from the animal research literature," and finally "corroborative literature . . . from the basic science fields of chemistry, toxicology, [and] surface science." 7 RT 822:8-25. In applying that methodology to *this*

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testimony established that even if Hopkins' MCTD had first arisen prior to her receiving the implants, "introducing silicone into her body" would have been "like pouring gasoline on a fire," further "inciting the immune system." 3 RT 111:21-22.

case, Dr. Kossovsky testified that he reviewed a wide range of material, including the deposition testimony of Hopkins' doctors, Hopkins' pathology slides and reports, Hopkins' medical records, the medical and scientific literature relating to silicone and autoimmune disease, and several Dow internal research studies on the immunological effects of silicone. 7 RT 813-814, 820. Dr. Kossovsky explained to the jury how he applied this standard methodology in coming to a decision about the cause of Hopkins' MCTD. 8 RT 904-05. Using this methodology he concluded that there exists a "high probability of a causal connection" between Hopkins' MCTD and her ruptured Dow Corning implants. 7 RT 823:1-4.

(2) Dr. Frank Vasey. Frank Vasey, M.D., is a board-certified rheumatologist and a full-time faculty member at the University of South Florida. 7 RT 691. He is a nationally recognized authority on clinical treatment of silicone-induced immune disorders and has testified before Congress, 7 RT 692, and has published on the subject. 7 RT 765. Dr. Vasey has personally seen over 200 patients with silicone-induced immune disorders. 7 RT 692. Dr. Vasey also testified that the preliminary results of an epidemiological study in which he participated "supported the existence of silicone disease." 7 RT 713:18-19.

Dr. Vasey based his testimony in this case on the classic "differential diagnosis" methodology employed by practicing, diagnosing physicians: on Hopkins' medical records, RT 7 RT 719-20, 724-25, and on his own "clinical experience with this disorder [and] the medical literature describing similar cases." 7 RT 723:3-5. After thorough analysis of all key sources of information he concluded that it was "more likely than not" that "Hopkins' MCTD was caused by her silicone implants." 7 RT 722-24.

(3) Dr. Marc Lappe. Marc Lappe, Ph.D, holds a doctorate in Experimental Pathology and currently teaches toxicology — the science of identifying poisons and their effects — at the University of Illinois Medical School. 2 RT 190:20-24. Dr. Lappe is a nationally recognized toxicologist and an authority on silicone and disease. He has testified before the FDA on

"risks of silicone," and in 1990 was appointed as a toxicological advisor to the FDA to "review data concerning the safety of silicone breast implants." 2 RT 202. Dr. Lappe has served as Chief Toxicologist of the California Department of Industrial Relations, where he was responsible for determining the safety of substances and materials for use by human beings. 2 RT 198. Throughout his career, Dr. Lappe has analyzed human and animal test data and has served on "human subject review committees that make decisions as to the acceptability of proceeding with direct testing or implantation of materials into humans." 3 RT 22.

Using the standard methodology employed in his field, Dr. Lappe reviewed "the medical reports and data on Mariann Hopkins," 2 RT 203:19, tissue tests, animal data, and the literature on silicone products, including every single internal Dow Corning study presented in the case. 2 RT 204:24-205:1, 240; 19 RT 2462:12-15. Based on careful analysis of these materials, Dr. Lappe concluded: "[T]he silicone which inevitably entered Mariann Hopkins' body at or before the observed time of rupture from these implants was the major causative factor in her mixed connective tissue disease." 3 RT 108:24-109:15. He reiterated: "There is no doubt in my mind that silicone was the major contributing factor to what we would call the pathogenesis or the development of this severe debilitating disease and its constellation of secondary effects." 3 RT 112:15-18.

REASONS FOR DENYING THE WRIT

I. THE FIRST QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT

In its first question presented, Dow Corning asks:

> May a federal appellate court after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ___, 125 L. Ed.2d 469, 113 S. Ct. 2786 (1993), uphold admission of expert scientific testimony when the district court refused to make any preliminary assessment of its scientific reliability and the proffered testimony met none of *Daubert*'s reliability criteria?

Pet. at i. But Dow Corning has not demonstrated that this question has something to do with *this case* and could be reached on the record below. Setting aside Dow Corning's undocumented assertions to the contrary, it is clear that Dow Corning made no objection at trial to the reliability of the methodology of Hopkins' experts, and that the district court considered and rejected each and every expert testimony objection that Dow Corning actually raised.

(1) The bulk of Dow Corning's expert testimony argument in its petition has, in fact, nothing to do with *Daubert* or the methodology of Hopkins' three experts who testified at trial. Instead, Dow Corning complains that the court of appeals erred in declining to grant its *summary judgment* motion which argued that Hopkins' evidence was *insufficient* (not inadmissible) to prove causation under California law. Dow Corning asserts:

> The panel undertook no review of the evidence presented by respondent to controvert petitioner's summary judgment motion challenging the sufficiency of her causation evidence to raise a triable issue of fact. If it had compared respondent's deposition testimony on causation with the requirements of *Daubert*, it should have been evident that her causation evidence was insufficient to permit her to go to trial.

Pet. at 18-19. Dow Corning contrasts the decision below with decisions of other circuits upholding summary judgments, Pet. at 19-20, and concludes that "petitioner's summary judgment motion should have been granted." Pet. at 20.

There are four reasons why this plea cannot be taken seriously as a basis for *certiorari*.

First, the Ninth Circuit "undertook no review" of the district court's denial of summary judgment on the sufficiency of the causation evidence for the simple reason that *it was not asked to do so*. In its docketing statement, Dow Corning assigned thirteen different points for appeal but excluded this summary judgment ruling. Dow Corning likewise failed to include the

point in any of its briefs or arguments, thereby waiving it.[9]

Second, review of the district court's denial of Dow Corning's summary judgment motion is now unavailable due to the intervening trial and jury verdict. After all, "the denial of a motion for a summary judgment because of unresolved issues of fact does not settle or even tentatively decide anything about the merits of the claim. It is strictly a pretrial order that decides only one thing — that the case should go to trial." *Switzerland Cheese Ass'n v. E. Horne's Market, Inc.*, 385 U.S. 23, 25 (1966). For that reason, "the denial of a motion for summary judgment is not reviewable on an appeal from a final judgment entered after a full trial on the merits." *Locricchio v. Legal Services Corp.*, 833 F.2d 1352, 1359 (9th Cir. 1987). This appears to be the uniform rule in the federal courts of appeals; indeed, in his *Locricchio* opinion Judge Sneed noted that "[a]fter considerable research, we have found no case in which a jury verdict was overturned because summary judgment had been improperly denied." *Id.*[10]

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[9] *See* Fed. R. App. P. 28(a)(4); *International Union of Bricklayers & Allied Craftsman Local Union No. 20 v. Martin Jaska, Inc.*, 752 F.2d 1401, 1404 (9th Cir. 1985) ("[W]e will not ordinarily consider matters on appeal that are not specifically and distinctly raised and argued in appellant's opening brief"). Obviously, Dow Corning's sudden desire for review of a summary judgment motion that it has ignored for more than four years hardly qualifies this as the kind of "exceptional case" worthy of review despite Dow Corning's failure to raise the issue in the court of appeals. *See, e.g., Kentucky v. Stincer*, 482 U.S. 730, 747 n.22 (1987); *Heckler v. Campbell*, 461 U.S. 458, 468 n.12 (1983); *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434-35 (1940).

[10] *See also Watson v. Amedco Steel, Inc.*, 29 F.3d 274, 1994 U.S. App. LEXIS 17036, *6-16 (7th Cir. 1994); *Black v. J. I. Case Co.*, 22 F.3d 568, 571-72 (5th Cir. 1994); *Johnson Int'l Co. v. Jackson Nat'l Life Ins. Co.*, 19 F.3d 431, 434 (8th Cir. 1994); *Lama v. Borras*, 16 F.3d 473, 476 n.5 (1st Cir. 1994); *Whalen v. Unit Rig, Inc.*, 974 F.2d 1248, 1250-51 (10th Cir. 1992), *cert. denied*, 113 S. Ct. 1417 (1993); *Lum v. City of Honolulu*, 963 F.2d 1167, 1170 & n.1 (9th Cir.), *cert. denied*, 113 S. Ct. 659 (1992); *Jarrett v. Epperly*, 896 F.2d 1013, 1016 (6th Cir. 1990); *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1573 (Fed. Cir. 1986), *cert. dismissed*, 479 U.S. 1072 (1987).

Third, if Dow Corning wished to obtain review of the sufficiency-of-the-evidence argument raised in its summary judgment motion on causation, it could have renewed the objection at the directed verdict stage. It elected not to do so, and this Court's settled Seventh Amendment jurisprudence therefore bars any sufficiency-of-the-evidence review on the causation issue. *See* note 1, *supra* (citing cases).

Fourth and finally, even if Dow Corning could revive its summary judgment motion in this Court, nothing in it is relevant to the *Daubert* inquiry that is the subject of the first question presented. In general, of course, *Daubert* concerns the admissibility of evidence in federal court, not its sufficiency under governing substantive law. More specifically, *Daubert* emphasized that in making Rule 702 admissibility decisions, "[t]he focus, of course, must be solely on principles and *methodology*, not on the conclusions they generate." 113 S. Ct. at 2797 (emphasis added). But Dow Corning's summary judgment motion attacked only the *conclusions* of plaintiffs' treating physicians (none of whom ultimately was called by Hopkins on the causation issue at trial). Dow Corning argued that these experts' conclusions were not expressed at the level of "reasonable medical probability" required under California law,[11] an issue that is simply not governed by Rule 702 as explicated in *Daubert*.

(2) In a further bid to convince this Court that the first question is actually presented by this case, Dow Corning claims that it "filed a motion *in limine* to exclude the testimony of respondent's three designated expert causation witnesses, Drs. Marc Lappe, Nir Kossovsky and Frank Vasey, because none of

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[11] *See* Defendant's Memorandum of Points and Authorities in Support of Motion for Summary Judgment, filed Nov. 20, 1989, at 7 ("The testimony of Plaintiff's treating physicians Dr. Donald R. Laub, Dr. Louis E. Pelfini, Dr. Stephen Gospe, and Dr. Hugh O'Neill McDevitt does not establish within a reasonable medical probability that Plaintiff's MCTD is causally linked to exposure to silicone"); *id.* at 10 (arguing that "more probably than not" standard must be met and that "not one [of Hopkins' physicians] is able to state within a reasonable medical probability that Plaintiff's condition is causally related to silicone or her breast implants").

their opinions was scientifically reliable or based on a methodology or technique accepted by any relevant scientific community." Pet. at 2. This claim is completely false. In fact, the *in limine* motion (which the district court denied; it did not refuse to rule on it) was a narrow one. The motion sought only to limit the *scope* of the three experts' testimony to their supposedly narrow areas of qualification and to restrict them from relying on certain pieces of data; Dow Corning made no effort to demonstrate that the *methodology* employed by these experts required the wholesale exclusion of the testimony. Hopkins documented this point in her Ninth Circuit brief without contradiction by Dow Corning.[12]

Because Dow Corning's *in limine* motion focused on the experts' qualifications (not on their methodology), it is understandable that — in rejecting Dow Corning's argument "that the district court erred in not holding a formal hearing" — the court of appeals stated that the district court was required only to

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[12] *See* Brief of Plaintiff-Appellee, 9th Cir. No. 92-16132, filed Feb. 1, 1993, at 46 & n.41:

> Dow's narrow *in limine* motion, the denial of which it now appeals, Dow Br. 47, invoked only *two* grounds for exclusion: (1) "that these experts do not qualify as experts under Federal Rule of Evidence 702" and "may attempt to offer expert opinion testimony which is beyond their specific and designated areas of expertise," and (2) that "under Federal Rule of Evidence 703, the Court should exclude any testimony by plaintiffs' experts where there is no acceptable or reliable basis for their opinion." Motion *in Limine* to Exclude Expert Testimony, filed June 18, 1991, at 2-3. *See also* Motion at 36 (limiting motion to Rules 702 and 703 and "requesting the Court to limit the subject matters" of testimony "to only those areas they were disclosed to testify regarding *and* in which they are qualified to testify") (emphasis in original). Nowhere in its motion did Dow argue that the ultimate expert opinions of Hopkins' experts should be excluded because the scientific methodology they employed was novel and not "generally accepted by the scientific community in the field in which the expert is testifying," Dow Br. 44-45, and Dow thus has waived this claim.

Nowhere in its reply brief, filed March 1, 1993, did Dow Corning suggest that its *in limine* motion attempted to prove flaws in the methodology of Hopkins' experts that would render their testimony entirely inadmissible.

"make a determination as to the proposed expert's qualifications." Pet. App. at 21. There is nothing "irreconcilab[le]" between this passage and *Daubert*; indeed, at the beginning of this same paragraph, the court of appeals made clear that "the trial judge must first determine, pursuant to Rule 104(a) and Rule 702, whether the expert is proposing to testify to scientific knowledge that will assist the trier of fact." Pet. App. at 20-21. Thus, Dow Corning engages in fantasy in suggesting, in its first question presented, that the Ninth Circuit upheld a district court's "refus[al] to make any preliminary assessment of . . . scientific reliability." Pet. at i.

(3) Finally, Dow Corning contends that its objections *during* trial "to the admission of respondents' expert witnesses should have been sustained." Pet. at 21. As Dow Corning belatedly documented in a post-argument letter brief, its "repeated objections to the testimony of plaintiffs' experts were overruled" at trial. Appendix B hereto, at **A6** n.5 (citations omitted). However, none of the 22 pages cited had anything to do with a *Daubert*-style analysis of *the methodology* of Hopkins' experts, as Hopkins documented without contradiction by Dow Corning. *See* Appendix C hereto, at **A14** n.3 (demonstrating that "the citations reveal minor objections," mostly to the form of testimony).

In the end, Dow Corning never preserved any *Daubert* issue below, so that the first question could never be reached by this Court even if the district court did refuse to rule when requested, which it did not. Dow Corning simply failed to object at trial to the *methodology* used by any of Hopkins' experts. Independently, there is no evidence in the trial record to contradict the testimony of Hopkins' experts that the methodology they used is valid and reliable, and indeed standard in their fields. *See* pp. 13-15, *supra*. Dow Corning makes no attempt in its petition to show the contrary; indeed, it does not even discuss the trial record, preferring to concentrate on the "evidence before the district court in ruling on the pre-trial motion." Pet. at 2; *see id.* 3-6 (reviewing deposition testimony only). Thus, the first question is not presented, and none of the objections actually raised by Dow Corning has any merit.

II. THE SECOND QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT

In its second question presented, Dow Corning attempts to raise the issue of the procedures by which a federal court, sitting in diversity, may review a punitive damage award. The gravamen of Dow Corning's argument is that such review is circumscribed by the Re-Examination Clause of the Seventh Amendment. Dow Corning's confused and contrived argument turns out to be quite radical. For example, Dow Corning openly argues that Fed. R. Civ. P. 59 is facially unconstitutional, at least in cases where the plaintiff seeks punitive damages — despite this Court's decision approving Rule 59 review in *Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 279-80 (1989).

Yet in the end there is no occasion to reach Dow Corning's proffered question because its argument was not raised below and thus is not properly presented here. Notably, Dow Corning did not include its new-found punitive damages point either in its petition for rehearing or in its motion to stay the mandate in the court of appeals, even though Dow Corning listed in the latter the grounds on which "[t]he Petition for Writ of Certiorari will be substantially based." Indeed, not only did Dow Corning fail to raise its constitutional claims below, but it pursued below precisely the *opposite* argument from what it advocates here.

(1) Dow Corning barely cites the procedural history of this case concerning punitive damages, or even the decision of the Ninth Circuit regarding that issue. In fact, in the court of appeals Dow Corning sought to invalidate the punitive damage award on the ground that it did not comport with the standard announced in *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22 (1991). *See* Pet. App. 28-30, 38; *see also* Appellant's Opening Brief, 9th Cir. No. 92-16132, filed Nov. 27, 1992, at 57 (arguing that "the standards and procedure for awarding punitive damages applied in this case do not meet the constitutional minima required by *Haslip*").

Although the court of appeals cited *Browning-Ferris* and Rule 59, it also performed a *Haslip*-style review that fully

satisfied procedural due process. The court enumerated the factors prescribed in *Haslip* for the judicial review of punitive damages. *See* Pet. App. 28-29. The court also discussed the substantive criteria for the assessment of punitive damages outlined in *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2721-24 (1993). *See* Pet. App. 29-30. The court of appeals explained that the award here was plainly justifiable under this precedent:

> The evidence presented at trial established that a large number of Dow silicone gel breast implants had been implanted in thousands of women. Each of these women was at risk of encountering the same fate from which Hopkins suffered. Therefore, Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, may properly be considered in imposing an award of punitive damages. Moreover, given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified. Coupled with the facts that Dow is a wealthy corporation and that Dow made a considerable amount of money from the sale of its implants, the jury's award of $ 6.5 million is reasonable in light of *TXO* and *Haslip*. Therefore, we conclude that Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award.

Id. at 30.

Dow Corning now evidently believes that it should never have received the benefits of *Haslip*'s procedures for judicial review in the first place because of the Seventh Amendment. But Dow Corning surely cannot be permitted to reverse course 180 degrees and to assign as error what it previously contended was required by due process. And, even if it could, it is difficult to

see how Dow Corning would have standing to assert that it enjoyed *more* procedures than it was constitutionally entitled to receive.

(2) Dow Corning makes no attempt to show that the question presented would make any difference in the outcome of this case. In fact, a California court may set aside a damages award only where it "appears excessive or . . . is so grossly disproportionate as to raise a presumption that it is the result of passion or prejudice." *Neal v. Farmers Ins. Exchange*, 582 P.2d 980, 990 (Cal. 1978). Like Rule 59 review, California "passion and prejudice" review is measured against the criteria applied by the jury. *See Las Palmas Assoc. v. Las Palmas Ctr.*, 1 Cal. Rptr. 2d 301, 323 (Ct. App. 1991) (review denied). Dow Corning's failure to analyze the concrete implications of the difference between state-court review and Rule 59 review means that its question presented is purely academic.

(3) In any event, Dow Corning's criticisms of judicial review in federal court are misplaced. Dow Corning admits that "[t]his Court has relied heavily on the lengthy history of the common law" in deciding whether punitive damage schemes comport with procedural due process, but maintains that "the common law has nothing to say about federal procedural rules." Pet. at 24. To the contrary: this Court recently indicated that "traditional practice provides a touchstone for constitutional analysis," and that the "the common law method of assessing punitive damages d[oes] not violate procedural due process." *Honda Motor Co. v. Oberg*, 114 S. Ct. 2331, 2335, 2339 (1994).[13] Although the common law may play a greater role in

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[13] Under the common law approach, judges "generally defer[] to the jury's determination of damages," and ask only whether "the damages are outrageous, and all mankind at first blush must think so," or whether damages are "so monstrous and excessive, as to be in themselves an evidence of passion or partiality in the jury." *Oberg*, 114 S. Ct. at 2336 (citations omitted). Although this Court did not definitively resolve precisely "what standard of review is constitutionally required," *id.* at 2341 n.10, this Court explained that:

> Although courts adopting a more deferential approach use different verbal formulations, there may not be much practical difference between

prescribing the *content* of state procedural rules than it does with respect to their federal counterparts, the *constitutionality* of federal and state rules must be judged by the same baseline of traditional practice. Indeed, in the very next section of its petition Dow Corning contends that, "[n]o less process is due under the Fifth Amendment than under the Fourteenth Amendment." Pet. at 25. If the common law approach is constitutional in state court, it is permissible in federal court as well.[14]

(4) Any claim that the standard California jury instruction on punitive damages is somehow inadequate is unavailable here because it was not pressed on appeal or passed on in the Ninth Circuit. Indeed, in a post-argument letter in the court of appeals, Dow Corning conceded that it had no remaining constitutional objections to affirmance of the jury's award in its entirety.[15] Nor is Dow Corning seeking review of the instruction in this Court. In truth, it is exceedingly difficult to determine what Dow Corning *is* seeking.

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review which focuses on "passion and prejudice," "gross excessiveness," or whether the verdict was "against the weight of the evidence." All of these may be rough equivalents of the standard this Court articulated in *Jackson v. Virginia*, 443 U.S. 307, 324 (1979) (whether "no rational trier of fact could have" reached the same verdict).

Id.

[14] If anything, the jury's powers were greater at the time of the adoption of the Fifth Amendment in 1791 than they were at the time of the adoption of the Fourteenth Amendment in 1868. *See Oberg*, 114 S. Ct. at 2348 (Ginsburg, J., dissenting).

[15] In a letter brief dated July 6, 1993, Dow Corning narrowed its argument to the claim that *if* it prevailed on its statute-of-limitations argument and thereby eliminated $367,000 of Hopkins' compensatory damages (her award for pain and suffering), and she recovered only "her out-of-pocket losses [$473,000], the amount of punitive damages awarded are so grossly excessive as to violate the substantive component of the Due Process Clause." Appendix B hereto, at **A9**. However, the Ninth Circuit ended up rejecting Dow Corning's statute-of-limitations argument, Pet. App. at 10-20, and upheld the compensatory award in full, *id.* at 27, thus mooting Dow Corning's sole remaining objection to the amount of the punitive damages award.

In any event, the jury instruction here[16] — which is the California pattern jury instruction for punitive damages — provided more guidance than the instruction approved in *Haslip*, which instructed the jury merely that, in setting the amount of punitive damages, "you must take into consideration the character and degree of the wrong as shown by the evidence and necessity of preventing similar wrong." 499 U.S. at 6 n.1; *see also Boyle v. Lorimar Productions, Inc.*, 13 F.3d 1357 (9th Cir. 1994) (the California instruction goes beyond the requirements of *Haslip*).

(5) Finally, Dow Corning asserts that "[t]he circuits are in conflict on the application of *Haslip* to punitive damage awards in diversity cases." Pet. at 25 (quoting argument heading). Dow Corning relies on but two cases for this rather sweeping statement, and its description of the cases is inaccurate.[17] In

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[16] "If you determine that punitive damages should be assessed against the defendant, in arriving at the amount of such an award, you must consider: (1) The reprehensibility of the conduct of the defendant. (2) The amount of punitive damages which will have a deterrent effect on the defendant in light of the defendant's financial condition. (3) That the punitive damages must bear a reasonable relation to the injury, harm, or damage actually suffered by the plaintiff." ER 302.

[17] The Eighth Circuit case on which Dow Corning relies — *Latham Seed Co. v. Nickerson American Plant Breeders, Inc.*, 978 F.2d 1493 (8th Cir. 1992), *cert. denied*, 113 S. Ct. 3037 (1993) — does not mention the Seventh Amendment, *Erie*, or any of the supposed problems with punitive damages review in diversity cases purportedly identified in Dow Corning's petition.

And Dow Corning fails to give this Court a complete account of developments in the Fourth Circuit after the decision in *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95 (4th Cir. 1991). In *Johnson v. Hugo's Skateway*, 949 F.2d 1338 (4th Cir. 1991), decided after *Mattison*, a panel of the court of appeals explained the limits of *Mattison*:

> We find misfounded concerns about the Seventh Amendment if such [post-trial] review is conducted by the district court. . . . [T]he district court would be conducting a narrow review based on the evidence in the record. We are not in the case of such review asking the district judge to consider factors that were not before the jury. Rather, we are simply suggesting that the district judge review the jury's factual determination to draw a *legal* conclusion (i.e., the reasonableness of the punitive

any event, both cases predate *Oberg* and *TXO*, which provide ample guidance to the lower courts as to the judicial review of punitive damage awards. And the instant case would in any event be an exceedingly poor vehicle to review the question presented, since Dow Corning *never asked* the court of appeals its view as to "the application of *Haslip* to punitive damage awards in diversity cases." Pet. at 25 (quoting argument heading).

CONCLUSION

The questions in Dow Corning's petition are not properly presented on the record of this case and are without merit. The prudential concerns Dow Corning raises about mass tort litigation have no logical connection to these questions and, in any event, do not apply to this case. Dow Corning's petition should be denied.

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damages award). Accordingly, this narrow review does not run afoul of the Seventh Amendment.

949 F.2d at 1351 n.6 (citation omitted and emphasis in original).

The Fourth Circuit reconsidered *Hugo's Skateway en banc*. The court did not expressly adopt the panel's analysis, but it squarely rejected the argument that a State's scheme for post-trial review is irrelevant to a federal court sitting in diversity. In carefully chosen language, the Court explained:

> if state law assigns the trial or appellate court a post-verdict role in assessing the reasonableness of a punitive damages award and specifies certain factors to be considered in making that assessment, . . . this body of substantive law must also be applied in federal court, but in a manner that permits consideration by *the jury* as the sole fact finder, rather than by the judge.

Johnson v. Hugo's Skateway, 974 F.2d 1408, 1417 (4th Cir. 1992) (*en banc*). Thus, there is significant doubt over the continued vitality of *Mattison* even in the Fourth Circuit.

Respectfully submitted,

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November 22, 1994

APPENDICES

APPENDIX A

Supplemental Authorities of Appellee,
9th Cir. No. 92-16132, dated June 29, 1993 . . . . . A1

APPENDIX B

Letter Brief of Appellant,
9th Cir. No. 92-16132, dated July 6, 1993 . . . . . A3

APPENDIX C

Letter Brief of Appellee,
9th Cir. No. 92-16132, dated July 15, 1993 . . . . . A10

APPENDIX A

LAURENCE H. TRIBE
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June 29, 1993

Ms. Cathy A. Catterson
Clerk, U.S. Court of Appeals
for the Ninth Circuit
121 Spear Street, 6th Floor
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RE: Supplemental Authorities, Hopkins v. Dow Corning Corp., No. 92-16132

Dear Ms. Catterson:

On behalf of appellee Mariann Hopkins, I wish to call to the attention of the panel (Judges Hug, Schroeder and Lay) two recent decisions of the U.S. Supreme Court.

First is TXO Production Corp. v. Alliance Resources Corp., No. 92-479, decided June 25, 1993 (slip opinion attached). In its reply brief at 29 n.51, and at oral argument, appellant Dow Corning argued that the decision in TXO might suggest a procedural deficiency with the post-trial review in this case. However, in TXO (unlike this case), the trial court did not even issue a written opinion explaining its ruling upholding the punitive damages award, but the Supreme Court, by a 6-to-3 margin, held that the "trial judge's failure to articulate the basis for his denial of the motions" was not a violation of procedural due process. Slip op. at 20 (Stevens, J., joined by Rehnquist, C.J. and Blackmun, J.); see also concurrence of Kennedy, J. and concurrence of Scalia and Thomas, JJ. Nor is anything else in TXO helpful to Dow.

Second is Daubert v. Merrell Dow Pharmaceuticals, Inc., No. 92-102, decided June 28, 1993 (slip opinion attached), relevant to Dow's argument in its reply brief at 17-20, and at oral argument, that the District Court's evidentiary decisions in this case must be reviewed de novo, and reversed, because "the steps each expert

used in moving from the raw data to his opinions [did not] follow[] a methodology that is generally accepted within the scientific community." Dow predicted at oral argument that the Supreme Court's decision in Daubert would vindicate its attack on the District Court. Nothing of the sort occurred. Daubert unanimously overruled the Frye "general acceptance" test. Slip op. at 4-8; see also partial concurrence of Rehnquist, C.J., and Stevens, J. By a 7-to-2 margin, Daubert also reaffirmed the "liberal thrust" of the Federal Rules of Evidence, slip op. at 8; agreed with Hopkins' brief at 53 that the focus of expert testimony admissibility analysis "must be solely on principles and methodology, not on the conclusions that they generate," slip op. at 14; and held that conclusions of experts may be challenged only through the adversary process, backed up by sufficiency-of-evidence analysis, slip op. at 15-16. Dow's strategy in the trial court of attacking the conclusions of Hopkins' experts rather than challenging any particular principle or methodology relied on by those experts, coupled with Dow's waiver of any sufficiency-of-evidence objection (Hopkins' brief at 55-56), renders Daubert of no help to Dow.

Sincerely,

(signature)
Laurence H. Tribe

cc: Shirley M. Hufstedler, Esq.
Frank C. Woodside, III, Esq.

APPENDIX B

HUFSTEDLER, KAUS & ETTINGER

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July 6, 1993

Honorable Proctor Hug
U.S. Circuit Judge
Honorable Mary Schroeder
U.S. Circuit Judge
Honorable Donald Lay
Senior U.S. Circuit Judge
United States Court of Appeals
for the Ninth Circuit
P. O. Box 547
San Francisco, CA 94101

In re: Hopkins v. Dow-Corning Corp., No. 92-16132

Dear Judges, Hug, Schroeder and Lay:

During the oral argument of the above-entitled case, I requested the Court's permission to file a supplementary brief to discuss the impact of Daubert v. Merrell Dow Pharmaceuticals, Inc., ___ U.S. ___ (1993) and TXO Production Corp. v. Alliance Resources Corp., ___ U.S. ___ (1993), neither of which had been handed down when this case was argued. I now renew my request and tender herewith this supplementary letter brief addressed to these two opinions as they apply to this case.

Introduction. In her letter, dated June 29, 1993, entitled "Supplemental Authorities", plaintiff states that Daubert does not

help defendant because at trial defendant only attacked the conclusions of plaintiff's experts rather than challenging the experts' methodology and that defendant waived any sufficiency of the evidence objection. The record contradicts the plaintiff's assertions.

In defendant's pretrial motion to exclude the testimony of plaintiff's causation experts, in its objections to the testimony of those experts at trial, in its motion for a directed verdict, and in its post-trial motions, defendant very specifically challenged the admissibility of the testimony on the grounds, among others, that the methodology used by these experts had no scientific basis and their opinions are not founded on any principles accepted by science. Defendant challenged the sufficiency of the evidence to go to the jury in its directed verdict motion because plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation. In its opening brief, defendant argued:

> "4. The district court prejudicially erred in permitting plaintiff to go to the jury on her personal injury claims because she failed to produce substantial evidence that her disorders and diseases were causally related to her prostheses" (Defendant's Opening Brief at 44).

The Daubert decision. The Supreme Court held that the "general acceptance" test of Frye was not the exclusive test for admitting expert scientific testimony after the Federal Rules of Evidence, but acceptance by an identified segment of the scientific community was relevant in determining admissibility. Slip Op'n at 8, 14. The Court was explicit that the district court must hold a Rule 104(a) hearing to determine admissibility of such testimony; the testimony is not admissible unless the expert is proposing to testify to scientific knowledge that will assist the trier of fact to understand or to determine a fact in issue.[1/]

[1/] "Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly

In reaching its Rule 104(a) determination, the district court must decide whether the proposed testimony is grounded in the methods and procedures of science.[2/]

Daubert validates defendant's contention that admission of plaintiff's scientific expert testimony was prejudicial error. Defendant's pretrial and post-trial motions and its objections at trial leave not the slightest doubt that defense counsel attacked the admissibility of plaintiff's expert witnesses precisely on the grounds that Daubert accepted. In each instance, defendant attacked the causation testimony proffered by Drs. Lappé, Vasey, and Kossovsky because the steps each used in forming his opinions were not based on existing scientific knowledge or on any scientifically accepted methodology, and none was validated.

The facts that the plaintiff suffered from MCTD and that the defendant's prostheses were implanted in her at some time during the course of her disease were never disputed. In reaching their respective conclusions, each of the experts relied on plaintiff's medical history, but that history contained nothing about the cause of her disease. Dr. Lappé reached his conclusion from his rereading of hundreds of defendants' animal studies. He was unable to cite any published literature, any study, or any experiment that agreed with his rereading of the animal studies, none that extrapolated the results of animal studies to human beings, and none that found a causal connection between implantation of medical grade silicone and human autoimmune disease. Moreover, Dr. Lappé, an experimental pathologist, was not qualified in the fields of human

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can be applied to the facts in issue. Slip Op'n at 12. [Emphasis added; footnote omitted.]

[2/] "The subject of an expert's testimony must be 'scientific . . . knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation. . . . [I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation - i.e., 'good grounds,' based on what is known. . . . [T]he requirements that an expert's testimony pertained to 'scientific knowledge' establishes a standard of evidentiary reliability." Slip Op'n at 9-10.

disease or in human reactions to implanted medical grade silicone.

Dr. Vasey had published a case study in which he hypothesized a possible connection between silicone-gel implants and autoimmune disease, but his sole methodology in turning his hypothesis into an opinion that the implants more probably than not caused her disease was his observations of his patients.[3/]

Dr. Kossovsky relied on an animal study that he had himself conducted, but he conceded that animal studies cannot be successfully extrapolated to human beings; he ultimately conceded that his opinion was based on an untested hypothesis.[4/]

The district court declined to hold a Rule 104(a) hearing. Throughout the proceedings below, the court was under the mistaken belief that its only obligation before admitting the proffered expert testimony was a preliminary determination of the experts' qualification.[5/] The district court's mistaken understanding of its obligation is most clearly revealed in the colloquy with defense counsel during the argument on defendant's post-trial motions in

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[3/] Such non-replicable, untested, non-peer reviewed observations are not acceptable in any scientific community as more than a basis for a hypothesis.

[4/] Extrapolating animal studies to human beings was held inadmissible in Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir. 1992), cited with approval in Daubert. Slip Op'n at 16. The Turpin court upheld summary judgment in favor of the manufacturer of a drug which plaintiffs contended had caused birth defects. "The decisive weakness in the plaintiffs' animal studies is that the factual and theoretical basis articulated for the scientific opinion stated will not support a finding that [the drug] more probably than not caused the birth defects here." 959 F.2d at 1359. In our case, as in Turpin, the proffered expert testimony was based on personal opinions, not science.

Turpin, as well as Viterbo v. Dow Chem. Co., 826 F.2d 420 (5th Cir. 1987) were cited and discussed in defendants' opening brief at 45, 46, 49, and in its reply brief at 22, 24.

[5/] Defendants' in limine motion to exclude plaintiffs' expert testimony is found, in part, in Excerpts of the Record at 148; the motion was denied by a telephone call from the district court's clerk. Defendant's repeated objections to the testimony of plaintiffs' experts (1 RT 227, 230, 239, 240, 250, 272; 3 RT 24, 52, 57, 75, 77, 95, 107; 7 RT 704, 709, 713, 722, 728, 741, 821, 825, 830) were overruled.

which the court expressed incredulity that it was obliged to go behind the face of offered expert testimony to determine whether there was any acceptable scientific basis for it.[9]

Defense counsel insisted that the court had the obligation to inquire into the basis of the testimony using a Rule 104 hearing at which the court should ask:

> "Is there any basis for that [opinion]? . . . [I]s there any literature? Are there any studies? Have you ever been taught thus and so? . . . [I]f the answer is . . . no . . . then I would submit that the opinion would be inadmissible, and that's what we have here. [T]here has to be some basis in science and that is what the Sixth Circuit is taking about . . . so that you don't just have junk science coming into court rooms. .

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[9] After the court expressed its view that as long as the witness was qualified as an expert, the only question was credibility of the witness to be decided by the jury, defense counsel pointed to multiple decisions of federal appellate courts holding that the court was required "to look behind his statements . . . and look to the rationale, the reason, the scientific basis for his opinions [and] when you do that . . . you find that there is no basis." Reporter's Transcript of the Hearing, April 27, 1992, at 5-7. The district court then asked:

> "The Court: ... Are you saying that its the duty of the trial judge when I hear expert testimony on complex subjects, that I have to ... say, 'well, gee, this guy is saying this astrophysics theory is such, let's look behind it.' Am I supposed to do that? ... I'm going to really see if this guy knows his stuff?' Is that my job? Yes or no?"
>
> "Mr. Woodside [defense counsel]: ... I believe the answer is yes. ..." RT at 7.

Citing the Sixth Circuit in Turpin, defense counsel said that court held that although judges should respect scientific opinion . . . nevertheless courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury."

The court again questioned its duty to inspect the reasoning of a qualified scientific expert, and defense counsel reaffirmed that the court had that duty:

> "Mr. Woodside: The law has evolved to the point where the bases of someone's opinion is something which must be looked into; and, therefore, appropriate inquiries [must be] made before trial, or after trial. [The court] has to [make] a determination." Id. at 8-9.

. ." Id. at 10-11.

The district court denied defendant's post-trial motion stating that it had "already ruled on those issues at trial, [and] I still believe that there is ample evidence in this trial from Drs. Lappé, Kossovsky, and Frank Vasey that was admissible and proper evidence to support the jury's verdict." RT 33-34.

Thus, defense counsel meticulously protected the record with respect to the erroneous admission of the testimony of plaintiff's expert witnesses, and defendant's briefs on appeal make the same points. The inquiries that defense counsel told the district court that it was required to make in determining the admissibility of the expert testimony and the sufficiency of the evidence were the very points that Daubert required:

> "[A] key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. 'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry."' "[Has] the theory or technique been subject to peer review and publication[?]" Slip Op'n at 13-14.[7/]

The district court's committed prejudicial error in admitting plaintiff's expert testimony without any Rule 104(a) hearing and without evidence of scientific reliability.

TXO Production Corp. This Court need not reach the punitive damage questions addressed in TXO Production Corp. and Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. ___ (1991) unless it has earlier decided that (1) the plaintiffs' personal injury claim was not barred by limitations, (2) no prejudicial error occurred in its

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[7/] The Supreme Court also explained that a "'reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community."' The Court added that an "unknown technique that has been able to attract only minimal support within the community . . . may properly be viewed with skepticism." Slip Op'n at 14.

refusing to follow Brown v. Superior Court, 44 Cal.3d 1049 (1988), and (3) no prejudicial error occurred in admitting plaintiffs' expert causation testimony because any one of these errors would require reversal.

After the plurality opinion in TXO Production Corp. about all that appears to be left of Haslip's due process analysis is that punitive damages must not be "so 'grossly excessive' as to violate the substantive component of the Due Process Clause." Slip Op'n at 13.

If, as defendant contends, plaintiff had no unbarred cause of action except for invasion of her economic interests, i.e., her out-of-pocket losses, the amount of punitive damages awarded are so grossly excessive as to violate the substantive component of the Due Process Clause.

Respectfully submitted,

HUFSTEDLER, KAUS & ETTINGER

DINSMORE & SHOHL

By (signature)
Shirley M. Hufstedler

SH:cjr

cc: Laurence H. Tribe, Esq.
Dan Bolton, Esq.

APPENDIX C

LAURENCE H. TRIBE
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July 15, 1993

Ms. Cathy A. Catterson
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for the Ninth Circuit
121 Spear Street, 6th Floor
San Francisco, CA 95105

RE: Hopkins v. Dow Corning Corp., No. 92-16132
(Before Judges Hug, Schroeder and Lay)

Dear Ms. Catterson:

On behalf of appellee Mariann Hopkins, I file this response in opposition to appellant Dow Corning's ("Dow") letter of July 6, 1993, in which Dow requested the panel's permission to file an extensive letter brief addressing the purported impact on this case of the Supreme Court's recent Daubert and TXO opinions. I respectfully request that this response be circulated to the members of the panel.

Dow's submission flouts the most basic rules of appellate advocacy: Dow raises arguments that have been waived; and it reargues points that have been fully briefed. As Part 1 of this letter explains, Dow advances arguments about admissibility and sufficiency that were available to it throughout this litigation but which Dow waived by failing to assert them at the proper time. As Part 2 explains, Dow has manufactured a "Rule 104(a) hearing requirement" that is utterly unsupported; Dow also selectively quotes from the post-trial hearing transcript in an effort to show that the District Court violated this non-existent requirement.[1]

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[1] As to the TXO decision, Dow's letter brief at [**A8-A9**] abandons all of Dow's previous objections to the punitive damages award except that of "gross excessiveness," and Hopkins certainly accepts Dow's concessions. However, the prior paragraph and the following paragraph are improper, as they merely reargue points earlier raised by Dow and answered by Hopkins.

1. Dow's Advancement of Waived Arguments Concerning the Admissibility and Sufficiency of Hopkins' Evidence

Dow's lengthy letter brief is targeted primarily to answering two observations made at the close of Hopkins' letter to the Court dated June 29, 1993:

> * Daubert does not help Dow because Dow chose at trial to attack only the conclusions of Hopkins' experts, rather than their methodologies.
>
> * Dow clearly waived whatever objections it may have had to the sufficiency of Hopkins' evidence.

A. Dow's Admissibility Objections

Dow's attack on the methodologies of Hopkins' experts is outrageous because it is totally new and totally unsupported by the record. Dow had an obligation to identify in its opening brief the legal arguments and record citations demonstrating an abuse of discretion by the District Court. Instead, with respect to the methodology issue, Dow waited until its reply brief to set forth a mere four citations to the record, none of which actually targeted methodology or presented any scientific proof relevant to the issue. See note 2, infra. Now, Dow seeks to add five times that number of citations in a post-argument letter brief, even though these new citations were obviously available to Dow when it filed its reply brief. In her briefing, Hopkins demonstrated that on this record there is no colorable challenge to any aspect of her experts' methodologies. The Daubert case — which addressed situations in which a party has objected to a scientific methodology, and which held that, even in such cases, general acceptance of the methodology is not necessary — is irrelevant here. Dow failed to put methodology at issue or even to introduce evidence bearing on methodology, and its last-gasp request that it be granted an exemption from accepted rules of appellate practice should be rejected.

Hopkins' observation that Dow "attack[ed] the conclusions of Hopkins' experts rather than challenging any particular principle or methodology relied on by those experts" in the District Court (Hopkins' June 29 letter; emphasis in original) was not a new argument and thus did not justify Dow's lengthy and argumentative response.

Indeed, Hopkins' mention of the methodology-conclusion distinction was merely a one sentence summary of a point argued in detail in Hopkins' brief, and highlighted directly by the Daubert decision.

Hopkins' brief specifically pointed out that Dow had filed a "narrow in limine motion," asking for limited relief (not wholesale exclusion of any expert's testimony) based on Dow's concerns about the qualifications of Hopkins' experts under Rule 702, and the reliance of Hopkins' experts on certain facts and data under Rule 703. Hopkins Br. at 46 & n.41. After demonstrating that the District Court had not abused its discretion or otherwise committed legal error in rejecting these narrow arguments (see Hopkins Br. at 48-52), Hopkins specifically argued that Dow had utterly failed to object below to the methodologies used by Hopkins' experts, and that there was no evidence in the record casting any doubt on the validity or reliability of those methodologies. Hopkins Br. at 52-55. This was hardly a passing observation; Hopkins addressed the point in detail:

> The methodology used by Hopkins' experts was the standard scientific technique, based on the use of all available data traditionally and regularly used by medical experts in determining causation. Even if the conclusion reached by Hopkins' experts that silicone leaking from Dow's breast implants caused or severely worsened her autoimmune condition could be characterized, in some sense, as "novel," the methodology used to arrive at that conclusion is generally accepted practice.
>
> * * *
>
> The methodology employed by Hopkins' experts in determining causation was carefully described by Dr. Kossovsky as "a standard established back in 1976." 7 RT 822. . . . Hopkins' other experts relied on similar methodology and reached the same conclusion. See p. 50, supra. Dow has offered no evidence or even argument that the methodology used by Hopkins' experts — including consultation of medical records, animal studies, case reports of silicone breast implants causing human autoimmune disease, and preliminary epidemiological data indicating a silicone-autoimmune linkage — is anything other than standard, accepted scientific practice.

Hopkins' Br. at 52-54 (emphasis in original; footnote omitted). See also id. at 50-51 n.46 (summarizing methodology used by each expert).

Dow specifically responded to this argument in its reply brief, in which it claimed that it had "objected both pretrial and during trial to the testimony of plaintiff's three expert witnesses on the causation issue because their opinions did not rest on any scientifically accepted basis." Reply Br. at 18 & n.31. Having thus responded to Hopkins' argument on this issue, Dow is not now entitled to bolster its position. In its reply brief, Dow chose to offer only four record citations, none of which actually demonstrated an objection to the methodology of the experts.[2] Moreover, Dow never offered any citations to evidence in the record (for example, testimony by its own experts) suggesting, let alone proving, any inadequacy in the methods used by Hopkins' experts. The testimony of Hopkins' experts that they used standard and entirely valid methodologies in rendering their opinions thus stood uncontradicted.

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[2] Dow's reply brief, at 18 n.31, listed without explanation the following record citations: 1 RT 107, 109; 2 RT 249-50; 7 RT 722, 821. But:

(1) **1 RT 107 and 109** did not even involve the testimony of any of Hopkins' three experts on causation; it involved testimony by a Dow sales representative concerning what Dow had told its sales force about possible dangers posed by its breast implants.

(2) **2 RT 249-50** involved a narrow Dow objection to Dr. Lappe's testimony, contending only that one comment about one aspect of several studies was "speculative."

(3) **7 RT 722** involved a preposterous Dow objection that Dr. Vassey's opinion regarding the cause of Mrs. Hopkins' disease was inadmissible on the ground of "inadequate foundation" because it was supposedly based "solely upon clinical observations that he has made in his practice." Dow offered no proof that clinical observation is an invalid scientific method, and it is hard to imagine that such proof could be offered. Moreover, the assertion that Dr. Vassey had relied "solely" on his clinical observations was completely repudiated by Dr. Vassey's own extensive testimony. Dr. Vassey's conclusions were expressly based on a "combination" of many factors. See 7 RT 710-712. See also 7 RT 702-09, 720, 722-26; Hopkins Br. at 23, 50 n.46.

(4) **7 RT 821** merely repeated an objection to Dr. Kossovsky's qualifications, earlier raised in Dow's in limine motion and overruled, and then abandoned by Dow on appeal.

Despite the full briefing and argument that has occurred with respect to the methodologies used by Hopkins' expert witnesses, Dow brazenly requests in footnote 5 of its letter brief (page **[A6]**) that this Court examine twenty-two new record citations on this point, which Dow now suggests (inaccurately, it turns out) will prove that the District Court ignored repeated direct attacks on the methodology used by Hopkins' three experts. That request should be rejected.[3]

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[3] Although Dow's letter brief is improper and should not be accepted for filing, it is worth noting that a review of Dow's twenty-two record citations reveals no objection to the methodologies used by Hopkins' experts, much less any evidence that there was anything unusual or invalid about those methodologies. Instead, the citations reveal minor objections by Dow, each of which was considered and ruled on by the District Court, mostly in Hopkins' favor (often after Hopkins' counsel had narrowed or otherwise altered the nature of the questioning). Dow's objections in footnote 5 of its letter brief fall into the following categories (note that Dow's reference to Volume 1 of the record is erroneous; the page citations noted appear in Volume 2):

(1) Testimony not relevant to any issue: **2 RT 239, 240; 3 RT 24, 77, 95; 7 RT 825**.

(2) Lack of qualifications on issue: **2 RT 227, 230; 3 RT 107**.

(3) No foundation laid for testimony: **7 RT 704, 722, 821**.

(4) Question asked and answered: **3 RT 52**.

(5) Question calls for speculation: **3 RT 24; 7 RT 728**.

(6) Unduly narrative answer: **7 RT 713, 830**.

(7) Testimony refers to hearsay: **2 RT 272; 7 RT 709**.

(8) Testimony is speculative: **2 RT 250; 7 RT 704**.

(9) No objection at all, or no ground stated for objection: **3 RT 57, 75; 7 RT 741**.

In light of the content of these twenty-two objections, Dow's belated assertion that it actually attacked the methodologies — rather than just the conclusions — of Hopkins' experts is mystifying. Dow confidently states that "[d]efendant's pretrial and post-trial motions and its objections at trial leave not the slightest doubt that defense counsel attacked the admissibility of plaintiff's expert witnesses precisely on the grounds that Daubert accepted" (Letter Brief at **[A5]**), but this conclusory statement provides no record citations, and no citations directed at methodology appear elsewhere in Dow's letter brief. Confidence is no substitute for accuracy.

B. Dow's Sufficiency Objection

Turning from admissibility to sufficiency, the Court will note that Hopkins' brief demonstrated that Dow waived any sufficiency argument on causation because Dow did not move for a directed verdict on this ground, even though it moved for a directed verdict on other grounds; moreover, Dow also failed to move for judgment as a matter of law on this ground. Hopkins Br. at 55-56 & n.54. As counsel for Hopkins specifically pointed out at oral argument without rebuttal by Dow, Dow's position in its reply brief, through its total silence on the point, was: "never mind."

Dow now ignores its past abandonment of any objection to sufficiency, and has the temerity to assert: "Defendant challenged the sufficiency of the evidence to go to the jury in its directed verdict motion because plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation." Letter Brief at **[A4]**. To substantiate this flimsy argument, Dow quotes a heading from its opening appellate brief which touches on sufficiency (id.), without acknowledging that Dow conceded the waiver point by failing to answer Hopkins' waiver arguments in its reply brief or in oral argument. Although this Court should not encourage Dow's behavior by permitting the filing of its letter brief, it is important to note that Dow's new argument is demonstrably false. Dow's motion and supporting brief for a partial directed verdict, filed Nov. 15, 1991 (ER 265), which was never enlarged upon orally (see 9 RT 1109; 16 RT 2229; 17 RT 2270, 2286), did not posit that "plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation." Letter Brief at **[A4]**. Dow's directed verdict brief said nothing about the causation issue, and nothing about the admissibility of any evidence.[4]

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[4] Moreover, Dow's novel idea that a motion for directed verdict or for judgment as a matter of law could be decided after truncating a trial record by "deleting" improperly admitted evidence is insupportable; the only post-trial remedy for evidentiary errors is a new trial. As the Supreme Court explained in Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 249 (1940), arguments "that the court erred in rulings on evidence and in refusing requested instructions" are proper on a Rule 59(a) motion for a new trial, but evidence

2. Dow's Attempt to Rewrite Rule 104(a) and Malign the District Court

Although Dow never objected below, or in its briefs, or at oral argument in this Court, to the procedure by which the District Court resolved Dow's evidence objections, it now argues, for the first time in a post-argument letter brief, that the District Court refused to conduct a "Rule 104(a) hearing" — whatever that is. Dow says that in Daubert the Supreme Court "was explicit that the district court must hold a Rule 104(a) hearing to determine the admissibility of [expert scientific] testimony," and Dow claims that "[t]he district court declined to hold a Rule 104(a) hearing." Letter Brief at **[A4, A6]** (emphasis added).

If Dow means to suggest that the Supreme Court has mandated a formal, separate proceeding on each objection to the admission of expert testimony, Dow is simply wrong. Nowhere did Daubert even intimate that Rule 104(a) requires any form of "hearing." Rather, the Supreme Court simply pointed out that under Rule 104(a), which requires that preliminary questions going to the admissibility of evidence "shall be determined by the court," the district court "must determine at the outset, pursuant to Rule

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for judgment" under Rule 50(b). "Each motion," it noted, "has its own office." Id. at 249. Given the Supreme Court's analysis, and given the unfairness of granting judgment as a matter of law against a party that relied on evidentiary rulings that are later determined to be erroneous, all four circuits that have reviewed district court decisions following the tactic suggested by Dow have reversed. See Jackson v. Pleasant Grove Health Care Center, 980 F.2d 692, 696 (11th Cir. 1993); Douglass v. Eaton Corporation, 956 F.2d 1339, 1343 (6th Cir. 1992); Dixon v. International Harvester Co., 754 F.2d 573, 579-80 (5th Cir. 1985); Sumitomo Bank of California v. Product Promotions, Inc., 717 F.2d 215, 218 (5th Cir. 1983); Midcontinent Broadcasting Co. v. North Central Airlines, Inc., 471 F.2d 357, 358 (8th Cir. 1973). There is nothing in this Circuit's law to support Dow's position; for example, the strong reliance concerns articulated in the above decisions are found in this Circuit's repeated holdings that JNOV points are waived if not preserved in a directed verdict motion at the close of all evidence. See, e.g., Murphy v. City of Long Beach, 914 F.2d 183, 186 (9th Cir. 1990); Lifshitz v. Walter Drake & Sons, Inc., 806 F.2d 1426, 1428-29 (9th Cir. 1986); Farley Transportation Co. v. Santa Fe Trail Transportation Co., 786 F.2d 1342, 1346 (9th Cir. 1985).

104(a)," whether the requirements of Rule 702 are met. Daubert slip op. at 12 (emphasis added). Neither Rule 104(a), Rule 702, nor Daubert requires that the district court hold any sort of "hearing," only that the district court "determine" the issue. The law of this Circuit is clear that a district court discharges its responsibility to make such determina-tions by considering the specific objections made and then admitting or rejecting the evidence. See, e.g., United States v. Kinslow, 860 F.2d 963, 968 (9th Cir. 1988), cert. denied, 493 U.S. 829 (1989); United States v. Gere, 662 F.2d 1291, 1294 & n.1 (9th Cir. 1981); United States v. Sangrey, 586 F.2d 1312, 1315 (9th Cir. 1978).

Given the complete lack of support for Dow's newly advanced "hearing requirement" theory, and this Court's settled precedent that no such hearing is required, Dow's attempts to malign the District Court's handling of Dow's evidentiary objections are nothing short of astonishing. Using selected and heavily ellipsed quotations, Dow tries in its letter brief — for the first time in this case — to paint a picture of a District Court stubbornly unwilling to look behind the experts' qualifications and shamefully failing to discharge its obligation to rule on specific admissibility objections. Although this argument should be summarily rejected as improperly made at this late stage of the proceedings, the argument is also completely unsupported by the record.

In reality, the "incredulity" expressed by the District Court in its colloquy with Dow's trial counsel was a response to Dow's effort to revive an already waived sufficiency argument. Dow maintained that the District Court should reject the conclusions of Hopkins' experts as not credible. Contrary to Dow's selective quotation of the post-trial hearing (see Letter Brief at **[A6-A8]**), the hearing did not even address the admissibility of Hopkins' expert testimony (see attached transcript covering this portion of hearing). This is not surprising: as noted earlier, Dow had not filed a post-trial motion concerning the admissibility of Hopkins' expert testimony. Dow ignored the issue in its directed verdict motion and its motion for judgment as a matter of law, and Dow addressed the causation issue in its new trial motion only to the extent of arguing that the verdict was against the weight of the evidence.

The only reason that the dialogue concerning expert testimony between the District Court and Dow's counsel occurred at all during the post-trial hearing was that, heedless of its previous waiver of the issue, Dow audaciously inserted a sufficiency objection to Hopkins' expert testimony on causation in its reply brief supporting its motion for judgment as a matter of law. Relying heavily on a Sixth Circuit sufficiency-of-evidence opinion that had just been announced, Dow's argument was not that the evidence was inadmissible, but that "the plaintiff's evidence on the causation issue is insufficient." Reporter's Transcript at 3; see also id. at 7-8.[5] Most importantly, nothing in Dow's post-trial reply brief or in its arguments at the hearing on its post-trial motions touched in any way on Rule 104(a). Dow's reference to Daubert's discussion of Rule 104(a) is thus irrelevant.

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[5] Dow relied on Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992). Turpin borrowed from administrative law doctrine to allow the district court to "judge for itself" the sufficiency of expert testimony after taking a "hard look" at the "validity of the reasoning process by which various competing qualified experts have reached their conclusions." 959 F.2d at 1350, 1352-53. Dow argued that "[h]ere, plaintiff's expert evidence suffers the same fatal flaws inherent in the expert testimony rejected as insufficient by the Turpin court," because one of Hopkins' experts had "[t]he earmarks of an evasive witness" who would "bob and weave," raising "a cloud of suspicion." Dow's Reply Memorandum in Support of Motions for Judgment as a Matter of Law or, in the Alternative, for a New Trial, filed March 16, 1992, at 4, 7-8. Despite the Turpin court's failure to consider the Seventh Amendment and Erie implications of substituting a judge's view on the credibility of an expert's conclusions for the jury's views, in a case arising under state law, Dow strenuously — and improperly, given its waiver — urged the District Court to adopt the Turpin approach to sufficiency-of-evidence analysis.

Addressing Dow's Turpin argument, the District Court modestly expressed misgivings about its ability, simply by virtue of being "appointed for life," to "really see if [a scientifically qualified expert] knows his stuff." Reporter's Transcript at 7. Even so, the District Court noted that "if someone comes here and says something that defies the law of science . . . I don't have to take that at face value." Id. at 6. To read into the District Court's rejection of Dow's Turpin theory on sufficiency a refusal by the District Court fully to examine all evidentiary objections is ludicrous.

For all the above reasons, Dow's request to have its letter brief filed should be rejected.

Sincerely,

(signature)
Laurence H. Tribe

cc: Shirley M. Hufstedler, Esq.
Frank C. Woodside, III, Esq.